Revision Record		
Revision	Date	Summary
0	2/24/05	Original issue
1	4/6/05	Revision to Introduction, page 2, last paragraph. LPR 308-00-00 and LA-UR-03-2355 will be rescinded after completion of nuclear facility safety bases assessments.
2	7/11/05	Incorporated LASO comments

Quality Steering Group Chair:	**Approval Signature:**	**Date:**
Carolyn A. Mangeng	Original Signature on File (Policy Office)	7/7/05
Laboratory Director:	**Approval Signature:**	**Date:**
John D. Immele for Robert W. Kuckuck	Original Signature on File (Policy Office)	7/8/05

Introduction

The *Quality Assurance Program (QAP)* is the approved institutional description of the overall management system at Los Alamos National Laboratory (LANL) that provides a level of confidence that both its business management and technical processes are effective and efficient.

The LANL QAP [hereafter the QAP] is issued under the authority of the Laboratory Director and reflects the values of LANL senior management. It is consistent with requirements of the LANL UC/DOE prime contract and LANL Governing Policies on performance, safety, and safeguards and security, and it promotes compliance with federal, state, and local regulations and codes.

This QAP establishes the LANL quality assurance program requirements for site-wide implementation and is to serve as the basis for LANL quality assurance program acceptability. It is designed such that implementation of the full scope of requirements as stated in DOE Order 414.1, *Quality Assurance* (current contractual version), constitutes compliance to nuclear safety quality assurance criteria required by 10CFR830, Subpart A, *Nuclear Safety Management Quality Assurance Requirements*. The QAP uses consensus standards to establish detailed quality assurance commitments for all LANL facilities and administrative and technical activities.

The QAP cites institutional documents that will support the implementation of the QAP. Referenced documents identified in *blue* text provide the direct link to the issued document. Documents identified in *red* are currently under development. The procedures prescribing the requirements for developing the institutional documents are LANL IMP 311, *Institutional Policies, Implementation Procedures, and Related Documents*, and ISD 311-1, *Manual for Preparing Policies, Procedures, and Related Documents*. The development and implementation of these documents, including references to forms, software, training, and evaluation methods have been included in a LANL QAP high level implementation plan that will direct the activities to achieve LANL QA Program compliance. The Implementation Plan is not attached to the QAP but will be submitted to and monitored by the National Nuclear Security Administration **(**NNSA) Los Alamos Site Office (LASO). NNSA LASO will be updated at least bi-annually by LANL management on the status of completed implementation plan actions.

The QAP will be updated annually and include verification of individual institutional document links to ensure references are updated.

The QAP subsumes all the performance criteria of LPR 308-00-00, *Institutional Quality Management*, and the responsibilities and program requirements contained within LA-UR-03-2355, *"Institutional Quality Management Program Description."* Upon completion of the assessment of nuclear facility bases and after appropriate changes are made, these two documents will be rescinded.

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Note: *Attachments may be revised without being resubmitted to NNSA LASO for approval.*

I. Purpose and Scope

The Code of Federal Regulations (10CFR830.3, *Nuclear Safety Management – Definitions)* define Quality Assurance Program (QAP) as "the overall program or management system established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work." This QAP is a description of the overall management system at Los Alamos National Laboratory (LANL) that assigns responsibilities and authorities, and describes key LANL policy and procedure requirements that communicate accepted methods for prescription, performance, and assessment of work.

This QAP establishes the LANL quality assurance program requirements for site-wide implementation and is to serve as the basis for LANL quality assurance program acceptability. It is designed such that implementation of the full scope of requirements as stated in DOE Order 414.1, *Quality Assurance* (current contractual version), constitutes compliance to nuclear safety quality assurance criteria required by 10CFR830, Subpart A, *Nuclear Safety Management Quality Assurance Requirements*. It also sets the LANL standard for management systems controls that are to be applied in work not affecting nuclear facilities or activities. The application of these business system controls is also supplemented by customers who work with LANL organizations to tailor the required level of assurance or confidence to mitigate risks and hazards of the customer's work scope. The less stringent applications of the QAP must be graded and justification for that grading must be appropriately documented.

The LANL Weapons Quality Assurance Program (WQAP) is part of the QAP and is referenced in Section III. This WQAP describes the flow down of quality assurance program requirements for LANL weapons activities compliant with DOE/NNSA QC-1, Revision 10, *Weapons Quality Policy*. Although administered as stated herein, the WQAP may be submitted for reviews and approval separately from this document.

II. Applicability of Quality Assurance Requirements

The requirements in this QAP apply to all work, including administrative and technical activities, and all members of the LANL workforce, including subcontractors and suppliers, through the flow down of requirements in LANL procurement contract terms and conditions.

II.1 LANL Quality Assurance Program Development and Implementation

II.1.1 Use of Quality Assurance Consensus Standards and Guidance

LANL uses the following quality assurance consensus standards (as appropriate) and guides as the foundation for establishing LANL's QAP requirements. A graded approach is applied for implementing the QAP requirements:

- ASME NQA-1-2000, *Quality Assurance Requirements for Nuclear Facility Applications* (for nuclear and radiological facilities, items serving vital safety systems, and activities including nuclear weapons production and manufacturing).
- DOE G 414.1-2A, *Quality Assurance Management Guide for Use with 10CFR830.120 and DOE O 414.1* (for non-nuclear-related facilities and activities, excluding research).

- ANSI/ASQ Z 1.13-1999, *Quality Guidelines for Research* (for non-nuclear research work including weapons physics research activities) as augmented by customer quality standards.

Additional quality assurance standards must be used as determined by customer (e.g., DoD, NASA, New Mexico Environmental Department [NMED]) needs and unique/specific work activities (e.g., development and use of safety and safety-related software). (Refer to Attachment 1, *Quality Assurance Requirements and Standards Crosswalk.*)

II.1.2 Application of the Graded Approach

LANL recognizes and supports the importance of applying quality assurance requirements in a graded manner by tailoring the formal controls for all work activities to reduce business and science risks.

Application of a graded approach is a process for ensuring that levels of analyses, management controls, extent of documentation, and actions necessary to comply with a requirement are appropriate, based on the following risk and hazard considerations:

- The relative importance to safety, safeguards, security, environment, and missions.
- The magnitude of any risk involved.
- The life-cycle stage of the facility, activity, or item (e.g., age, status, and condition of the facility or process).
- The programmatic mission of a facility or activity (complexity of products or service involved).
- Any unique characteristics of the facility, activity, or item.
- The relative importance to managing radiological and nonradiological hazards.

Application of a graded approach at LANL must be consistent with the requirements in the *Graded Approach for Work Activities* institutional document and defined and documented in procedures, Integrated Work Documents (IWD), or work plans. A graded approach *cannot* be used to avoid compliance with federal, state, and local regulations.

LANL must also implement work processes for controlling S/CI, tools for reducing incidents of S/CI and software graded to the work and associated hazards supporting the requirements contained in the *Suspect/Counterfeit Items* institutional document, LIR 308-00-04, *Procurement Quality*, LIR 308-00-05, *Software Quality Management*, and the *Software Quality Assurance Program*, Attachment 2 of this QAP.

II.1.3 Exceptions or Exemptions to QAP Requirements

The QAP requirements *cannot* be waived. Requests for exceptions to or exemptions from QAP requirements at a directorate/division-level must be justified in writing and submitted to the appropriate Associate Director and the Quality Steering Group Chair for approval.

Note: Directives or standards required by law or contract are mandatory unless DOE/NNSA has granted a temporary or permanent exemption from that requirement in writing. Criteria for granting an exemption to a nuclear safety requirement are specified in 10CFR820, *Procedural Rules for DOE Nuclear Activities*, Subpart E – *Exemption Relief*.

II.1.4 QAP Format, Content, and Subcontractor Requirements

To facilitate the direct link to quality assurance requirements, elements of the QAP (including suspect/counterfeit items [S/CI] controls and safety software quality requirements) correspond to the Contractor Requirements Document (CRD), Attachment 2, of DOE O 414.1 (current contractual version). The QAP commits to compliance with DOE O 414.1 (current contractual version) for all LANL activities including the flow down of requirements to subcontractors at any tier to the extent necessary to ensure overall LANL compliance with DOE O 414.1 (current contractual version). The flow down of subcontractor requirements must be prescribed to a level of detail and specificity that addresses the technical and quality requirements in formal change-controlled documents.

II.1.5 Integration of ISMS (Integrated Safety Management Systems) and QA (Quality Assurance) into Work Management

The QAP supports the implementation of DOE P 450.4, *Safety Management System Policy*, and DOE P 450.5, *Line ES&H Oversight Policy*, as required in the Contractor Requirements Document (CRD), Attachment 2, of DOE O 414.1 (current contractual version) and 10CFR830, Subpart B, *Safety Basis Requirements* (for nuclear facilities and activities), through the integrated safety management system described in LA-UR 98-2837, *Los Alamos National Laboratory Integrated Safety Management Description Document*.

The requirements apply to all LANL work and workers and are implemented in accordance with the LANL integrated work management process, IMP 300, *Integrated Work Management for Work Activities*. Workers are empowered under this program to identify and mitigate hazards on specific work activity bases.

To ensure work control processes are implemented, IWDs, work permits, and procedures are developed to integrate the work definition, hazards, risks, and controls for work authorization and communication to the affected workers at the work activity level. Work will only proceed subsequent to management approval of work documents addressing ISMS criteria.

Attachment 3 of the QAP describes the integration of ISMS and QA into work management. The integration is demonstrated in the planning, performance, and assessment phases of work.

II.2 QAP Approval

The QAP is reviewed and updated at least annually by the Institutional Quality Management Group (PS-1) prior to submittal for approval by the Quality Steering Group Chair, to ensure compliance with requirements documents and regulations. After the Quality Steering Group Chair and Laboratory Director approvals, the QAP is submitted to the NNSA LASO for review and approval identifying the changes, pages affected, justification for changes, and the basis for concluding that the changes meet the requirements. Minor editorial changes do not need to be approved by the NNSA LASO.

Quality assurance supplemental documents (e.g., division quality assurance programs, project quality assurance programs) that are developed by directorates/divisions, including projects and programs managed at a project/program director level, are submitted for written approval to the Quality Steering Group Chair to ensure consistency with the QAP requirements.

Consistent with DOE/NNSA QC-1, Revision 10, specific LANL quality assurance plans that supplement the QAP or WQAP (e.g., for the Waste Isolation Pilot Project and LANL Nevada Test Site weapons work) are submitted to the Quality Steering Group Chair for written approval and do not need to be submitted to the NNSA LASO for approval.

II.3 Development and Approval of Directorate and/or Division Quality Assurance Programs/Plans

Directorate- and/or division-level quality assurance programs/plans must be developed describing the organization's specific approach to implementing the QAP requirements and must include roles, responsibilities, and interfaces of individuals performing QA functions. Division-level quality assurance programs/plans must be submitted to the appropriate Associate Director for approval prior to submittal to the Quality Steering Group Chair for approval.

III. Quality Assurance Reference Documents

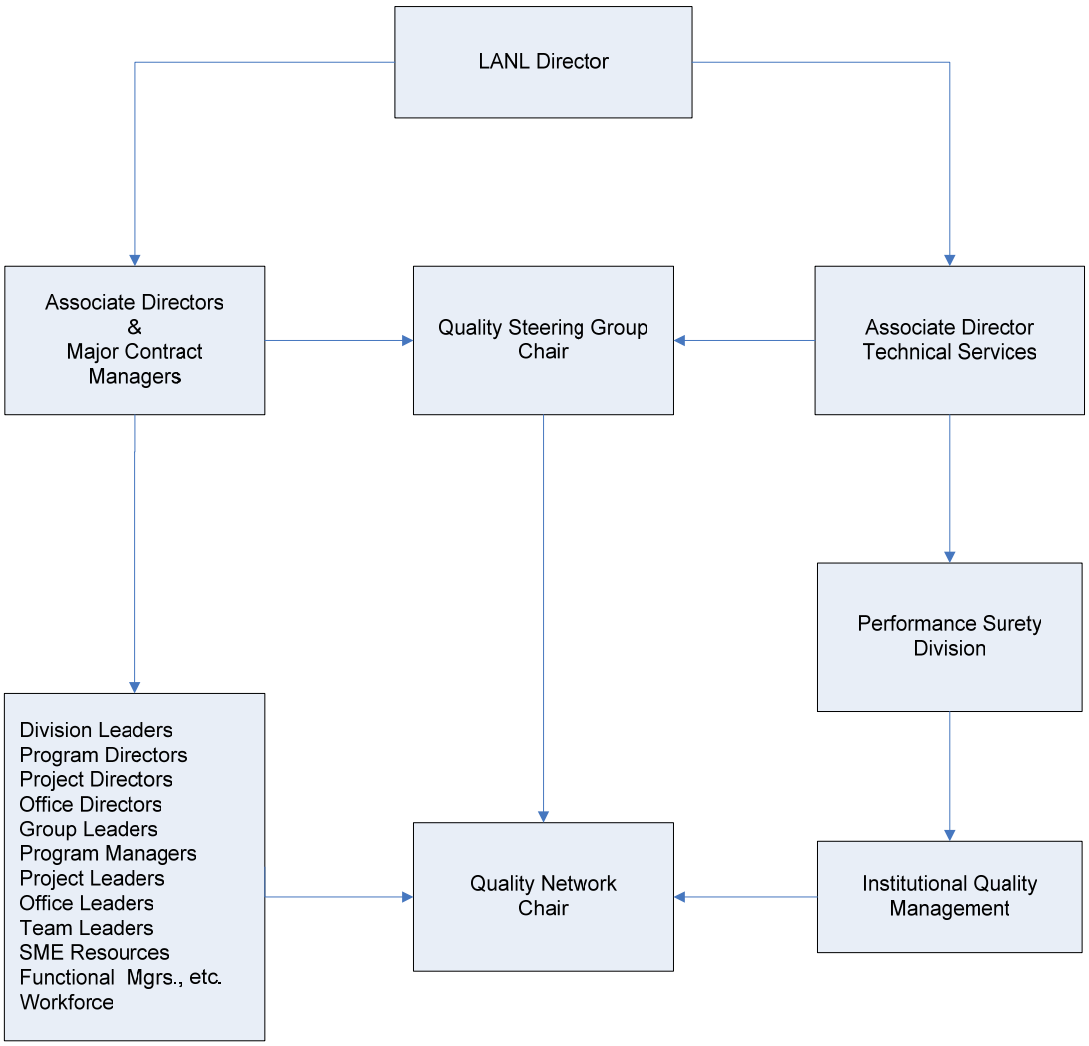
- *Los Alamos National Laboratory Weapons Quality Assurance Program*
- DOE G 414.1-1A, *Management Assessment and Independent Assessment Guide for use with 10 CFR, Part 830, Subpart A, and DOE O 414.1A, Quality Assurance*
- DOE G 414.1-3, *Suspect/Counterfeit Items Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1B, Quality Assurance*
- DOE G 414.1-4, *Safety Software Guide for Use with 10 CFR 830, Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance*
- ANSI/ISO/ASQ Q 9001-2000, *Quality Management System – Requirements (for non-nuclear activities)*

IV. Quality Assurance Functional Responsibilities and Accountabilities

Quality assurance is a shared interdisciplinary *function* performed by management and workers responsible and accountable for producing items, performing research and development, performing activities and services, and independently verifying that items, activities, and services comply with specified standards and requirements. See Figure 1 for the *LANL Quality Management Organization Structure*, showing the authorities and reporting lines for individuals performing quality assurance functions.

Quality Management Organizational Structure at LANL

Figure 1



IV.1 Laboratory Director

- Retains the ultimate authority and accountability for the QAP and its implementation.
- Ensures that overall institutional vision, values, standards, and management systems that define the QAP are established and documented in policies and procedures.
- Ensures that resources necessary for effective implementation of the QAP are provided.
- Fosters an environment that promotes and supports the identification of issues and resolution for continuous quality improvement.
- Appoints the Quality Steering Group Chair to administer the QAP.
- Approves the QAP and supports its implementation.

IV.2 Quality Steering Group Chair

- Reports directly to the Laboratory Director.
- Appoints LANL's subject matter experts for quality assurance requirements and implementation issues, unless otherwise designated by the Laboratory Director.
- Represents the Laboratory Director in providing leadership, direction, and management of the QAP.
- Represents LANL with NNSA LASO and other external organizations regarding quality assurance requirements, QAP implementation, and assessments/audits.
- Ensures the development, implementation, assessment, and improvement of the QAP. As supported by the Institutional Quality Management Group (PS-1) and Performance Surety Division, the Quality Steering Group (QSG) and the Quality Network:
- Approves the QAP and submits it to the Laboratory Director for final LANL approval then to NNSA LASO for approval.
- Approves directorate/division and program quality assurance supplemental documents and QAP implementation plans.
- Provides the official institutional interpretation of commitments to contractual and regulatory quality assurance requirements.

IV.3 Quality Steering Group

- Oversees and guides the development and implementation of the QAP.
- Endorses the QAP institutional support documents.
- Reviews and interprets quality documents and policy issues.
- Provides recommendations regarding quality assurance policy issues to support the Quality Steering Group Chair key decisions.

IV.4 Associate Directors

- Account for directorate compliance with quality assurance requirements (e.g., 10CFR830, Subpart A, DOE O 414.1 (current contractual version), and DOE/NNSA QC-1).

- Determine and provide resources (e.g., budget, personnel, materials) to accomplish required work activities.
- Serve as the directorate representative on the Quality Steering Group.
- Appoint directorate and/or division representatives to serve on the Quality Network.
- Ensure the flow down and effective implementation and enforcement of quality assurance requirements within their directorates.
- Ensure that applicable quality standards and quality requirements are identified for the work to be performed.
- Develop/approve directorate/division and program quality assurance supplemental documents (where applicable) and QAP implementation plans within their directorates.
- Ensure that LANL customer and programmatic requirements are integrated into the scopes of work activities (e.g., ISM, Integrated Safeguards and Security Management [ISSM], Conduct of Operations).
- Foster an environment that promotes identification and comprehensive correction of quality issues (e.g., S/CI) that support continuous quality improvement.
- Support the identification and recommendation for policy, process, or procedure changes that improve quality and efficiency within their directorates and/or throughout LANL.
- Perform and provide a summary management assessment report to the Quality Steering Group Chair and Laboratory Director annually that evaluates the adequacy, effectiveness, and implementation of management systems performance within their directorates.

IV.5 Performance Surety Division

- Provides formal operations and oversight for interdivisional and inter-directorate services.
- Develops and implements integrated management systems that document performance indicators, measure performance status, and regularly report results to LANL senior management (e.g., issues management, authorization basis).

IV.6 Division Leaders/Program, Project, and Office Directors

- Determine quality assurance program requirements based on work scopes and develop and/or approve quality assurance program documents and implementation plans within their divisions/programs/projects/offices.
- Approve quality assurance supplemental documents and implementation plans within their divisions/programs/projects/offices (where applicable).

IV.7 Institutional Quality Management Group (PS-1)

- Provides procedures, processes, tools, and quality training to assist organizations in implementation of the QAP.
- Serves as a resource to systematically manage potential quality concerns, issues, and problems.
- Provides inspection, quality assurance compliance and performance assessments, and program development support services to LANL.
- Reviews directorate and/or division quality assurance supplemental documents and QAP implementation plans for compliance with the QAP requirements.
- Coordinates and chairs the Quality Network and disseminates quality-related information to Quality Network members.
- Manages the Suspect/Counterfeit Items (S/CI) program by providing a point of contact responsible for implementation of the S/CI program and for receipt and dissemination of S/CI information notices.
- Independently assesses the QAP implementation utilizing a risk-based process to determine assessment scope.

IV.8 Quality Network

- Assist in the development and implementation of the QAP.
- Share quality-related information (e.g., S/CI, defective items, product recalls) among workers within directorates, divisions, programs, and offices and identifies and helps to resolve multi-organizational quality issues.

IV.9 Assessments Group (AA-2)

- Independently assesses QAPs and quality assurance areas based on an annual analysis of institutional risk.
- Reports assessment results directly to the organizations and programs assessed, the Quality Steering Group Chair, Laboratory Director, and the UCOP Chief Auditor.
- Validates corrective actions.

IV.10 Members of the Workforce (at all levels)

- Implement their organization's procedures to meet QAP requirements.
- Comply with administrative and technical work control requirements.
- Identify and report issues to the responsible manager for resolution and continuous improvement for the work being performed.
- Seek, identify, and recommend work methods or procedural changes that would improve quality and efficiency.

V. Quality Assurance Criteria

The quality assurance requirements addressed in this QAP include the 10 quality criteria (i.e., management, performance, and assessment) on the following pages. The quality assurance consensus standards identified in Section II.1.1 have been embedded in the 10 quality criteria. The 10 quality criteria must be applied to LANL work as best business practices for planning, managing, achieving, and assessing work in a safe, secure, and compliant manner. This is further described in Attachment 1, *Quality Assurance Requirements and Standards Crosswalk*. To optimize business practices, the requirements within a criterion are to be applied using a graded approach tailored to the level of hazards and risks imposed by the nature of the work and by the functions required of the work product. LANL implementation documents are identified in the appropriate criterion.

MANAGEMENT CRITERIA

Criterion 1 - Program Development

1.1. Summary

The intent of program development is to assure that LANL missions are effectively accomplished through clear assignment and effective communication of roles, responsibilities, and authorities for program and process development, execution, and maintenance. Communication of LANL contract and mission requirements into management-approved institutional documents instills values that are incorporated within business processes and communicated to workers via implementation procedures and tools. Policies and procedures also stipulate process ownership and establish metrics to assess program effectiveness for accountability that are directly coupled to mission success. This criterion describes the management planning process, business strategies, organizational structure, levels of authority, lines of communication, functional responsibilities, and interfaces for those organizational elements that perform and assess LANL work.

1.2 Process Requirements

The QAP establishes requirements for the management of effective safety and quality controls for facilities and activities necessary for appropriate planning, staffing, design, procurement, construction, testing, operation, and maintenance. The assignment of responsibilities must be based on requirements that ensure that safety, reliability, and performance are maximized through the application of management systems that minimize risks and hazards posed by the work. Process controls include analysis and planning (prior to the initiation of work activities); imposition of effective policies, schedules, and procedures that provide details of activities; and the application of qualified workers, materials, and equipment.

1.3 LANL Roles and Responsibilities

The LANL organizational structure (*LANL Organizational Chart*) describes the current Directorates, Divisions, Programs, and Offices. The roles and responsibilities for managing, performing, and assessing work must be clearly defined within a hierarchy of governing LANL documents (*LANL Document Hierarchy*) that are developed for specific functions and work activities. The three tiers of LANL governing documents are managed, maintained and controlled by the Laboratory Policy Office (*Policy Office*).

1.3.1 Laboratory Director

- Ensures effective oversight of all LANL work and maintains overall responsibility for regulatory and contract compliance.

1.3.2 Quality Steering Group Chair

- Ensures the development, implementation, assessment, and improvement of the QAP. As supported by the Institutional Quality Management Group (PS-1) and Performance Surety Division, the Quality Steering Group (QSG) and the Quality Network:
  - Approves the QAP and submits it to the Laboratory Director for final LANL approval then to NNSA LASO for approval.
  - Approves directorate/division and program quality assurance supplemental documents and QAP implementation plans.
  - Provides the official institutional interpretation of commitments to contractual and regulatory quality assurance requirements.

1.3.3 Associate Directors

- Report to the Laboratory Director.
- Ensure implementation of the requirements specified in the QAP.
- Ensure that work, workers, and management systems are reviewed and qualified for their specific applications.
- Provide oversight of LANL and subcontractor/supplier work to include subcontractor and supplier activity assessments, reviews, surveillances, and inspection and test monitoring activities.
- Stop work or suspend work when quality, work risks, or hazards are not effectively controlled.

1.3.4 Division Leaders/Program Directors/Office Directors

- Report directly to their respective Associate Directors.
- Apply quality principles to achieve compliance through directorate, division, and/or program quality assurance supplemental documents.
- Stop work or suspend work when quality, work risks, or hazards are not effectively controlled.

Note: Quality compliance is generally measured at division functional levels.

1.3.5 Members of the Workforce (at all levels)

- Stop work or suspend work when quality, work risks, or hazards are not effectively controlled.

1.4 LANL Quality Assurance Planning, Development, and Implementation

LANL must use risk-based planning and control mechanisms (e.g., a graded approach) to achieve strategic and tactical goals. A senior level board, the Institutional Assurance Board, forms the core of a risk-based management prioritization program. The board meets regularly to assure effective issues management, from issue identification through systemic corrective action. Programs, projects, and high priority actions are aligned to assure that scope, cost, and schedule are consistent with planned resource allocation and work authorization.

Information provided for strategic planning must include customer-negotiated scopes of work, descriptions of the fiscal year's budget appropriation, and other applicable work costs. This information also includes additional risk and hazard analyses developed in accordance with identified procedures, cost benefit/risk reduction, work breakdown structure (WBS) development, deliverables identification, scheduling assumptions, provisions for performance measurement, allowable cost and schedule variance, and budget account controls. Necessary changes to work activities are managed through identified procedures for work execution and configuration change control.

Policies, procedures, and contracts must be used to manage and control the interfaces required between the organizations, suppliers, and subcontractors. These documented agreements provide a formal methodology for program execution and contract administration, establishing communication lines, specifying documentation requirements, and enabling required accountabilities.

Criterion 2 - Personnel Training and Qualification

2.1 Summary

The intent of personnel training and qualification is to assure that both LANL workers and subcontractors assigned to work are properly qualified to perform their assignments in an efficient, safe, secure, and compliant manner and are trained to maintain proper qualifications.

2.2 Process Requirements

Personnel assigned to work must receive appropriate training prior to performing work. This training ensures that personnel are properly equipped to work safely and securely and to achieve and maintain proficiency through the life of the work activity (LIR 300-00-04, *Laboratory Training: Essential Requirements*). This LIR is consistent with DOE O 5480.20A, *Personnel Selection, Qualification and Training Requirements for DOE Nuclear Facilities.*

2.2.1 Training Methodology

Training must be developed using a systematic approach tailored to meet the current specified work activity. Training methods must include formal training conducted by qualified instructors, briefings conducted by management-approved personnel, required readings, workshops, seminars, awareness training, etc.

2.2.2 Initial Training Requirements

Personnel assigned to perform activities must have the education, skills, knowledge, and abilities (SKAs), experience, and training commensurate with the functions associated with their work. Personnel must receive initial training established to address work-specific risks and hazards associated with their roles and responsibilities.

2.2.3 Validation and Verification of Training

Responsible managers must identify the qualification requirements, training needs, and proficiency maintenance requirements of personnel assigned to work. Qualifications and training to meet these requirements must be validated and verified.

2.2.4 Training Documentation and Record Keeping

Documentation requirements for training must be identified by responsible managers and includes training course listings of personnel assigned to the work cross-referenced to the training required for work authorization. Required training must be documented (e.g., Employee Development System [EDS] database), which provides objective evidence that the required training was delivered and that the personnel trained acknowledge receipt and understanding of the training material.

2.2.5 Qualification and Certification

A qualification and certification program must be established and implemented in accordance with approved procedures. Responsible managers must determine at the start of each activity those individuals who must be qualified and those who must be certified before they are allowed to assume the roles and responsibilities of their position. Certification must be based on formal evaluation and verification of skills by proficiency testing. 2.2.6 Refresher Training

Responsible managers must assure that personnel complete refresher training to maintain and enhance SKAs appropriate to work risks and hazards. Refresher training must be developed to assure that proficiency is maintained to continue worker eligibility as necessary. Ineligible personnel are precluded from work activities.

Criterion 3 - Quality Improvement

3.1 Summary

The intent of quality improvement is to establish an appropriate means for the identification, cause and corrective action determinations, and reporting of issues that result from defects, noncompliance, or inefficient practices. Corrective action processes are established to assure effective disposition and correction/treatment of issues to obtain long-term benefit and to continuously strive to provide better products to customers by seeking better processes for the initiation, implementation, completion, and close out of work.

3.2 Process Requirements

3.2.1 Detecting and Preventing Quality Problems

Responsible management must encourage all workers to pursue quality improvement in every aspect of their work by applying lessons learned, analyzing work for unacceptable risk, and by continuously reporting and preventing or mitigating problems that may affect the quality of the work performed. When a potential or real quality problem is detected, established procedures must be followed to report, analyze, and acceptably mitigate the problem and improve the governing process.

Workers must be responsible for identifying quality problems and for reporting developing or existing conditions adverse to quality. Inspection, testing, acceptance, occurrence reporting, surveillance, management assessments, and independent oversight activities are designed to identify, document, evaluate, and correct quality concerns, deficiencies, and nonconformances. These activities must be performed in accordance with approved procedures and must be documented as dictated by procedure.

All quality deficiencies must be documented, cause(s) determined and corresponding corrective actions determined, corrected, verified, and closed out in accordance with a formal corrective action management system.

Processes used by LANL to anticipate, detect, or report potential or real problems include, but are not limited to, the following:

- Inspections and Tests (*Inspection, Test, and Acceptance* institutional document).
- Nonconformance Reports (*Nonconformance Reporting* institutional document).
- Unreviewed Safety Questions and Potentially Inadequate Safety Analyses (LIR 300-00-06, *Nuclear Facility Safety Basis*, OST 300-00-06B, *LANL Unreviewed Safety Question Screening and Determination Procedure*, and OST 300-00-06C, *LANL Unreviewed Safety Question Screening and Determination Standard*).
- Security Incidents (LIR 406-00-01, *General Security, Attachment 14 - Reporting Safeguards and Security Incidents*).
- Suspect/Counterfeit Items (*Suspect/Counterfeit Items* institutional document).
- Management Walk-Arounds (LIR 307-01-03, *Management Safety Walk-Arounds*).
- Management Assessments (LIR- 307-01-01, *Management Assessment Program*, and LIR 307-01-05, *Issues Management Program*).
- Price-Anderson Amendments Act (PAAA) Enforcement Program (LIR 308-00-07, *LANL PAAA Enforcement Program Requirements*).
- Occurrence Reporting and Processing (ORPs) Program (LIR 402-130-01, *Abnormal Events*, and OST 402-130-01, *Laboratory Occurrence Reporting Requirements/Guidance*).
- Radiological Incidents and Reporting (LIR 402-700-01, *Occupational Radiation Protection Requirements*).
- Safety Concern Program (LIR 307-01-04, *Safety Concern Program*).
- Assessments and Surveillances (*Independent Assessments* institutional document).
- Lessons Learned (LANL Lessons Learned Database, *http://dominoapp.lanl.gov/lln/lldocs.nsf/main*, and the LANL Mirror, *http://mirror.lanl.gov/*).
- Stop Work and Restart (LIR 401-10-01, *Stop Work and Restart*).

Note: Documents cited above may change or be rescinded. As documents are changed or rescinded, links to the documents will be updated.

3.2.2 Resolving and Correcting Quality Deficiencies or Discrepancies

Conditions adverse to quality must be identified promptly and require the implementation of immediate corrective action, requirements for control of the items and services to prevent inadvertent use or further processing of nonconforming items. If conditions adverse to quality cannot be corrected expeditiously, compensatory measures must be implemented pending completion of the identified corrective action. In the case of a significant condition adverse to

quality, the cause of the condition must be determined and corrective action taken to preclude recurrence.

Corrective actions to resolve quality deficiencies must include the following documentation:

- Investigation to determine the extent of the adverse condition or similar conditions (e.g., is this an example of a widespread problem?).
- Determination of the cause and a corrective action plan for similar conditions.
- Determination of the actions and objective evidence necessary to preclude recurrence of the condition, as warranted (e.g., should procedures, standards, or training need to be changed?).
- Correction of the affected larger population and system (e.g., procedures, standards, or training).
- Verification and documentation of the effectiveness and objective evidence of appropriate correction.
- Thresholds for collective significance based on repetitive quality deficiencies (e.g., nonconformance reports and audit finding trends).

3.2.3 Feedback and Continuous Improvement Issues

When identifying and resolving quality deficiencies and process improvements identified through formal assessments, LANL responsible managers must:

- Utilize the Corrective Action Reporting process as described in LIR 307-01-05, *Issues Management Program*.
- Conduct trend analysis and issue Lessons Learned Reports as warranted.

Specifically for S/CI quality issues, the LANL S/CI point of contact must:

- Collect, maintain, and disseminate accurate information on S/CI and associated suppliers.
- Report S/CI status to the NNSA LASO.

Criterion 4 – Document Control and Records Management

4.1 Summary

The intent of a document control system is to provide a systematic and deliberate process for the development, review, approval, communication, use, and revision of formal documents (e.g., instructions, procedures, drawings, and contracts) to prescribe processes, specify requirements, or establish design. The intent of a records management system is to establish methods for the identification, generation, authentication, and maintenance of objective evidence of work activities.

4.2 Process Requirements

4.2.1 Document Control

4.2.1.1 Identifying Documents

Work must be planned starting with a thoroughly specified work scope and analyzed for risks to add documentation regarding mitigation of the risks. Documents determined by the responsible manager to be subject to increased levels of analyses, management controls, documentation, or actions must be placed under formal change control.

Work procedures, instructions, plans, drawings, or other appropriate controlling documentation must include or reference, where applicable, proven codes and standards and reference applicable tolerances, including qualitative or quantitative acceptance criteria. Higher hazard work (such as work with the potential to cause radiological harm or work governed by authorization bases documentation) must require strict specification of all work controls in work plans or procedures.

4.2.1.2 Preparing Documents

Responsible managers must ensure that documents that prescribe work activities (e.g., instructions, procedures, drawings, etc.) are prepared, reviewed, approved and, when required, revised in accordance with approved organization or institutional procedures for document control. The procedures prescribing the requirements for developing documents are LANL IMP 311, *Institutional Policies, Implementation Procedures, and Related Documents,* and ISD 311-1, *Manual for Preparing Policies, Procedures, and Related Documents.*

4.2.1.3 Controlling Documents

Documents must be prescribed and approved by the responsible manager for use. The version of the document approved for use must be identified to workers as the version requiring compliance during current and planned work activities. Changes to controlled documents must be subjected to commensurate levels of review and approval as the original document consistent with the requirements contained in the *Document Control* institutional document.

4.2.1.4 Document Storage

Documents, recording media, or electronic documents under specific control systems or with proliferation restrictions (e.g., classified removable electronic media [CREM]) must be subjected to additional institutional requirements.

4.2.2 Records Management

4.2.2.1 Identifying and Preparing of Records

A records management plan must be written for each LANL division. Divisions generating records are responsible for identifying, preparing, validating, categorizing and designating the retention period of the record. Upon completion and designation as a record requiring retention, the record must be transmitted to long-term storage in accordance with the approved division or institutional procedure (LIR 308-00-02, *Laboratory Records Management*) for records management.

4.2.2.2 Receiving, Indexing, and Classifying of Records

Completed records must be reviewed for acceptability and uniquely identified. This identification must be entered into a database or log, which identifies the record type (e.g., epidemiological, radiological, medical, human resources, security, etc.) and the record location within the record system. Acceptable records must be legible, authenticated by a valid signature, and must have retention schedules based on record type and expected future use.

4.2.2.3 Storing, Preserving, and Safekeeping of Records

Each division must maintain and store its own records. Access to records must be limited to workers authorized on a need-to-know basis. Records transferred to archival or long-term storage must be processed in accordance with the requirements contained in the records management LIR and division record management plans. Computer hardware and software that are used to prepare, store, maintain, index, and access records must be controlled to ensure records protection from loss or damage and to ensure that the records are accounted for and retrievable.

PERFORMANCE CRITERIA

Criterion 5 - Work Processes

5.1 Summary

The intent of work process controls is to assure that work activities are planned and performed using approved policies, procedures, instructions, etc., under controlled conditions. When items and materials are required to accomplish specified functions, work controls must include maintaining and controlling items and equipment to prevent damage, loss, or deterioration, to ensure their proper use, and to ensure that the equipment is calibrated and maintained.

5.2 Process Requirements

5.2.1 Ensuring Availability of Standards, Procedures, Personnel, Facilities, and Equipment

Responsible managers must ensure that, as applicable:

- Work requirements are fully planned and documented using LANL-approved industry standards, current information, and documentation.
- Work performed by subcontractors and suppliers is monitored.
- Procedures are developed and approved prior to performance of the work.
- Activity hazards are identified according to hazard analysis and controlled through prescribed procedures or integrated work control documents.
- Qualified and trained workers are assigned to conduct work operations.
- Permits and authorizations are identified and completed consistent with requirements contained in LIR 210-01-01, *Site and Project Planning*.
- Materials and equipment are controlled to ensure risks to mission, safety, security, and the environment is managed (e.g., Master Equipment List [MEL] for nuclear activities, special processes).

The following list represents the primary functional programs and/or documents that support and implement work control processes throughout LANL:

- Integrated Work Management Program (IMP 300, *Integrated Work Management for Work Activities*, LIR 402-860-01, *Lockout/Tagout for Personal Safety*, and LIR 402-860-02, *Locking and Tagging Equipment, Machinery, and Systems*).
- Nuclear Safety Basis Program (LIR 300-00-05, *Facility Hazard Categorization*, LIR 300-00-06, *Nuclear Facility Safety Basis*, and LIR 300-00-07, *Nonnuclear Facility Safety Basis*).
- Conduct of Operations Program (LIR 310-00-00, *Conduct of Operations*).
- Laboratory Science Program for Research & Development.
- Waste Management Program (LIR 404-00-02, *General Waste Management Requirements*, and LIR 404-00-03, *Hazardous and Mixed Waste Requirements*).
- Maintenance Management Program (LIR 230-04-01, *Laboratory Maintenance Management Program*).
- Occupational Radiation Program (LIR 402-700-01, *Occupational Radiation Protection Requirements*).
- Emergency Management Program (LIR 403-00-01, *Los Alamos National Laboratory Emergency Management*, LIR 402-100-02, *Hazardous Waste Operations and Emergency Response Training Requirements*, and EMP 403-00-01, *LANL Emergency Management Plan*).
- Institutional Software Quality Management Program (LIR 308-00-05, *Software Quality Management*, and the *Software Quality Assurance Program*, Attachment 2 of this QAP).

Note: Documents cited above may change or be rescinded. As documents are changed or rescinded, links to the documents will be updated.

5.2.2 Retaining Control of Work Processes and Special Processes

Work processes must be conducted in accordance with approved instructions, procedures, or drawings to ensure that:

- Work process parameters are controlled.
- Safe and secure work practices are employed.
- Specified environmental conditions are maintained.
- Records of qualified workers, equipment, and process procedures are maintained.
- Requisite quality parameters are verified.
- The end product is produced to customer expectations in a safe, effective manner.

Each work activity not normally attributable to the skill of the craft must be performed under approved (repetitive process) procedures or must be under specific work plans analyzed for risks and hazards such as the IWD process under IMP 300, *Integrated Work Management for Work Activities*, prior to implementation.

Special processes that control or verify quality, such as those used in welding, heat-treating, and nondestructive examination, must be approved by the responsible manager for specific applications. These processes must be performed in accordance with documents that include or reference procedures, workers, and equipment qualification requirements. Conditions necessary for accomplishment of the special process and acceptance criteria must be included

in the work documents. (Click here for the *Special Processes* institutional document.)

Work process controls for S/CI must include:

- Development and implementation of policies and procedures that prevent the introduction and use of S/CI through engineering involvement, design, procurement, testing, inspection, maintenance, evaluation, disposition, reporting, trend analysis, and lessons learned work process controls.
- Training to inform responsible managers, supervisors, and workers on S/CI processes and controls, including prevention, detection and disposition of S/CI.
- Identification of S/CI through inspection, test and surveillance.
- Restriction of S/CI use to only those items found to be acceptable through engineering analysis and formal disposition process. (Click here for the *Suspect/Counterfeit Items* institutional document.)

Detailed test and inspection plans must be developed by the responsible manager to outline the processes for ensuring that the intent of the design is met. Submittals from subcontractors must be reviewed for acceptability, and their acceptability and use must be identified. Accountability for application of special processes to vital safety systems and other high risk applications must be maintained through various verification activities performed by qualified workers. These activities must include independent inspection, assignment of hold points, and witnessing or inspection/test verification in accordance with Criterion 8 of this document, and surveillance and assessment conducted in accordance with Criterion 9 of this QAP.

5.2.3 Identifying and Controlling Items

Items must be identified and controlled to ensure their proper use and must be maintained to prevent their damage, loss, or deterioration. Items must meet functional and operational requirements consistent with design specifications in accordance with the requirements in the *Inspection, Test & Acceptance* institutional document. When mandated by requirements documents (e.g. design, procurement, construction, or maintenance), the material or item pedigree including inspection, testing, and operating status, must be retained as history. Identification necessary to provide traceability for an item, from initial receipt through installation and use, must be placed on the items or on documents traceable to the items. When items such as labels, tags, ink stamps, or paints are used to identify items, provisions must be made to protect the identification from deteriorating.

5.2.3.1 Subcontractors and LANL Maintenance Workers

The subcontractor or LANL maintenance organization must be responsible for maintaining item, equipment, and material identification and accountability (e.g., weld filler material and weld cover gas) during work activities. Workers must verify installation compliance through inspection, monitoring, surveillance, post-installation testing, and assessment activities conducted in accordance with Criterion 8 and Criterion 9 of this QAP.

To prevent the use of incorrect S/CI or defective items, physical identification must be used when possible. Identification must be clear, legible, and indelible. When physical identification is impractical, workers must employ physical segregation, procedural control, or other means. The marking material and method should not affect the overall function or performance of the controlled item. The correct identification of items must be verified and documented before they are released for

processing, use, storage, or shipping.

Subcontractors and maintenance workers must be responsible for the activities cited in this paragraph as stipulated in contract and work documents, approved directorate and/or division supplemental quality assurance documents, and/or the subcontractor's QAP (refer to the Institutional Evaluated Suppliers List [*IESL*]).

Subcontractors and maintenance workers must verify and document that adequate item identification is maintained from receipt through turnover via inspection, monitoring, surveillance, testing, and assessment activities conducted in accordance with Criteria 7 through 10 of this QAP. A thoroughly planned control system that is equivalent to the LANL lockout/tagout process (LIR 402-860-02, *Locking and Tagging Equipment, Machinery, and Systems*) must be maintained to mitigate facility and activity hazards and risks.

5.2.3.2 Measuring and Test Equipment

Measuring and test equipment (M&TE) must be calibrated, controlled, and maintained in accordance with the requirements contained in the *Laboratory Calibration Program* institutional document or in its absence, the manufacturer's recommended standards. A graded approach for the calibration of equipment must be applied, depending on the critical nature of the equipment and the desired end product.

5.2.4 Packaging, Handling, Storing, and Shipping of Items

5.2.4.1 Packaging, Handling, and Shipping of Items

Responsible managers must assure that any items shipped in association with a specific work activity, including items returned to the vendor, must be shipped in accordance with the requirements contained in LIR 405-10-01, *Packaging and Transportation*, or the manufacturer-approved shipping procedures.

5.2.4.2 Storing Items

Responsible managers must maintain integrity of quality-affecting items (items whose failure could result in nuclear hazards, environmental contamination, significant monetary loss, or critical work requirements not being met) through appropriate warehousing, storage, and oversight. Oversight activities for verification include inspection, monitoring, surveillance, or assessment conducted in accordance with Criterion 8 and Criterion 9 of this QAP.

5.2.5 Monitoring Process Activities

Responsible managers must monitor work processes for compliance with specific work requirements. In addition to the normal work control processes, responsible managers must continuously monitor work processes through various verification activities as outlined in work-specific acceptance test/inspection plans. These activities include independent inspection and monitoring conducted in accordance with Criterion 8 of this QAP, and surveillance and assessment conducted in accordance with Criterion 9 of this QAP.

Criterion 6 - Design

6.1 Summary

The intent of design control is to assure that design items and processes are developed using engineering principles and appropriate technical standards, that appropriate technical and industrial standards are incorporated into the design work or changes, that design interfaces, including organizational and design product interfaces, are identified and controlled, that design adequacy is verified by independent, multi-discipline reviews before implementation, and that changes to the original design receive reviews and approval comparable to the reviews and approvals of the original design.

6.2 Process Requirements

6.2.1 Design Process

Design engineers must prescribe and document facility and programmatic design activities on a timely basis. The level of detail must be as necessary to permit the design process to be carried out, to permit verification that the design meets requirements, and to assure that the required inspections and tests are specified and include appropriate acceptance criteria. Appropriate technical and industrial standards must be identified and documented by technically qualified persons, and the selection of these standards must be reviewed and approved by technically qualified persons. Design output documents must be adequate to support facility, product, and process/activity design, construction, installation, operation, modification, and maintenance.

Engineered items must be identified by process design documents. The systems, structures, and components identified in the hazard and risk analyses must be linked to the quality requirements for hazard/risk mitigation in the design specifications, drawings, and process procedures (e.g., DOE O 420.1A, *Facility Safety*).

Installation criteria must be established for facility and process equipment. These criteria must include any special tools and/or torque requirements for components and should be clearly defined in the manufacturers' product documentation (manuals, specifications), process specifications, procedures, and/or design drawings and documents. (LIR 220-03-01, *Engineering Standards*, OST 220-03-01-EM, *Engineering Standards Manual*, LIR 240-01-01, *Facility Configuration Management*, and the *Conduct of Engineering* institutional documents).

6.2.2 Design Input

The design process must translate design input, including functional and operational requirements, design bases documents, and existing program requirements (e.g., needed permits and codes/standard requirements), into design output that is technically correct and meets end-user requirements (e.g., LANL Engineering Standards Manual requirements).

Workers responsible for design must verify that the design output meets the design input requirements and that any deviations have been documented and approved. Design requirements for items and processes must be specified in writing and included in the appropriate design documents for review and approval.

6.2.3 Design Interface Controls

Design interface controls must be established to formally communicate design information across organizational boundaries to indicate design document status for use (e.g., status

indicator stamps) and the responsibilities for further evaluation, review, and/or approval.

Multidisciplinary reviews must be conducted at designated intervals to preclude improper designed product coordination and sequencing for application, installation, or fabrication/production.

6.2.4 Design Analyses

Design analyses must be sufficiently detailed so that a technically qualified person can independently review and comprehend the analyses and verify the adequacy of the results.

6.2.5 Design Output

Design output such as drawings, specifications, scientific investigation results, calculations, and hardware/software development data must be established in written documents that have unique identification and revision status. Design output documents must relate to the design input requirements, codes, and standards and include sufficient detail to facilitate the design verification/review process. Design document changes must receive levels of processing and reviews/approvals equal to those for the original design document. Current document revisions must be maintained to reflect as-built conditions.

6.2.6 Design Verification

Design processes must include design verification as a formal, documented process performed by technically knowledgeable persons who are not involved in the original design. The purpose of design verification is to establish that the resulting item, process, system, structure, or component achieves its intended/specified use as defined in design and/or performance requirements. Design verification must be required prior to approval and implementation of the design. Design verification methods include, but are not limited to, design reviews (or peer reviews for research), alternate calculations, or performance of qualification tests.

6.2.7 Design Change Controls

Design changes support desired changes in the configuration and operational capability of facility and process equipment, typically involving hardware changes. The method for initiating and controlling (screening, reviewing, and approving) changes must be specified by approved procedures (e.g., OST 300-00-06B, *LANL Unreviewed Safety Question Screening and Determination Procedure*).

Design changes, including field changes and nonconforming items designated as “use-as-is” and “repair,” must be controlled by measures commensurate with those applied to the original design. These items must be retained as “as-built” records or transcribed onto approved as-built records. Temporary modifications to designs and system configurations must receive the same level of control as permanent modifications.

As-built drawing requirements must be identified and developed, reviewed, and approved for the specific processes. From the process hazard analyses, these drawings must identify the components that are important to safety. As-built documents pertinent to high-energy systems and components (e.g., explosives, high pressure, natural gas, or high voltage) must require increased levels of review prior to approval. The responsible manager must maintain an index of and have access to current process equipment drawings. For research activities, only those

documents addressing designs/design work that are accepted for further development or application must be subject to these controls.

6.2.8 Computer Software Controls for Design

Computer software utilized for safety analyses, design substantiation, and instrumentation and control must be controlled and verified as follows:

- In the case of commercial software used for analysis and calculation purposes, care must be taken that the original program is not degraded. A copy of the original program must be stored in a protected location.
- Software written or modified by the user must be verified as to its ability to meet design specifications. Dry runs, modeling, or test equipment must be used to ensure the outcome.
- Software owners must document software programs, including each revision and modification, and this documentation must be controlled as permanent records.
- Hardware configurations used to display software pertinent to safety analyses, design substantiation, and instrumentation and control must also be documented with its associated software.
- Software used in design substantiation calculations must be treated the same as in any design activity that requires the development of design requirements/specifications, design validation, and verification and acceptance testing to assure that the software meets the requirements/specifications. A change control process must be developed to ensure configuration control for critical process software. A master copy of this software must be controlled.

Software is controlled in accordance with the requirements in LIR 308-00-05, *Software Quality Management*, and the *Software Quality Assurance Program*, Attachment 2 of this QAP.

Criterion 7 - Procurement

7.1 Summary

The intent of the procurement process is to assure that functional and operational requirements are appropriately translated to specifications and contractual documents; suppliers are evaluated and monitored to assure they provide and continue to provide items and services that meet established requirements; test and inspection requirements are identified and documented to mitigate risks; material packaging, handling, shipping, and storage requirements are communicated to the supplier through contractual requirements; and purchased items, services, and pedigrees are verified to assure they meet established requirements and performance expectations.

The University of California Laboratory Procurement Standard Practices Manual sets forth the Standard Practices (SPs) and policies that comprise the approved procurement system used at LANL. The SPs are based on prime contract requirements and current regulations, requirements, and approvals under the prime contract between the DOE and the University of California.

In addition, procurement specifications are developed to identify technical and quality assurance requirements, to prevent the introduction of S/CIs, and to enable inspection to verify that items meet established requirements.

Procurement quality requirements are contained in LIR 308-00-04, *Procurement Quality* (also the *LANL Quality Assurance Supplement 838.c* form, *QA Form 838c*), the *Procurement Requestor's Manual*, LIR 405-10-01, *Packaging and Transportation*, and SP 46.1, *Subcontract Quality Assurance.*

7.2 Process Requirements

7.2.1 Controlling Procurement

Procurement activities must be planned and documented at the earliest practical time to provide interfaces for ensuring compatibility and uniformity during the procurement process. Procurement activities must be performed in accordance with documented procedures to ensure that a systematic approach is used in procurement processes.

The extent of procurement control must appropriately reflect the relative importance, risks, and hazards associated with the items or services being procured. Control must be consistent with the requirements imposed upon the supplier by the procurement documents. Objective evidence of quality must be required in accordance with specifications listed in the procurement documents. Standard Practice (SP) 7.1, *Planning*, describes LANL's acquisition planning system.

Controls must be formalized for specifying and awarding items or services to other LANL divisions or DOE laboratories, consistent with the controls imposed on external suppliers. Subcontractors may be required to purchase items and materials for work. The procedures and procurement documents used for procurement of components, parts, or services must be subject to review and approval by qualified workers before use. The review process must be implemented in accordance with identified procedures.

7.2.2 Initiating and Controlling Procurement Documents

The procurement cycle begins when the need for an item or service has been identified and a decision has been made to proceed with its purchase. Before initiating procurement, qualified workers must determine what quality controls (e.g., test, inspection, documentation) are to be applied. Procurement requirements must be developed to support elimination or mitigation of the risks/hazards associated with the item or service and for effecting the desired level of quality control.

A procurement document comes under control when it is initially released for review. Changes to the procurement document subsequent to initial release for review must be subjected to a review and approval process commensurate with the original document. The performance of the review and approval process must be documented for each change. The procedure for issuing and documenting changes and modifications to subcontractors is described in SP 43.1, *Contract Modification*.

7.2.3 Procuring Quality Items and Services

Procurement requires quality controls when initial analyses identify that failure of the item or service being procured could result in:

- Significant hazards or risks exist to workers, the facility, the public, or the environment.
- Failure to meet critical work requirements,

- Failure to meet product qualifications.

In addition, when purchasing items or services requiring imposition of regulatory codes or standards, consistent institutional requirements must be contractually invoked (e.g., technical standards, quality standards, and critical functional and operational characteristics).

Subcontractors, when required to purchase items and materials for work, must maintain procurement quality controls evaluated by qualified LANL workers for compliance with these requirements. The procedures and procurement documents must be subject to review by qualified workers before use.

7.2.4 Reviewing and Approving Procurement

Qualified workers must ensure that procurement requests incorporate all necessary specifications, codes, acceptance criteria, testing requirements, and reports, or other product qualifying criteria. After appropriate technical/quality reviews, designated group level or equivalent workers must approve the procurement documents before forwarding them for procurement.

7.2.5 Selecting Subcontractors, Vendors, and/or Suppliers

Initial selection and continued qualification of subcontractors, vendors, and/or suppliers must be based on an evaluation of their ability to provide items and/or services that meet requester needs and specifications. Selection must be coordinated among the requesting organization, and technical and quality reviewers by the LANL procurement division. Using the graded approach, subcontractors, vendors, and/or suppliers must be evaluated against formally established evaluation criteria for the following:

- Capability and/or history of providing the item or service.
- Current state of the subcontractor's, vendor's, and/or supplier's quality assurance program.
- Technical and quality capability as determined by evaluation of the subcontractor's, vendor's, and/or supplier's facility and the implementation of their quality assurance program.

The evaluation and approval of the supplier must be completed prior to awarding the contract as described in LIR 308-00-04, *Procurement Quality*.

Standard Practice (SP) 9.1, *Subcontractor Responsibility*, describes the procedures for ascertaining the prospective subcontractor's capability to perform a proposed subcontract.

7.2.6 Specifying Criteria for Acceptance of Items and Services

Methods for accepting items and services must be identified and incorporated into the contractual agreements in coordination with the requesting organization and the LANL procurement division. Methods for item or service acceptance may include:

- Factory tests.
- Technical or peer review of information.
- Physical inspection.
- Acceptance of Certificates of Conformance (for evaluated suppliers).

- Post-installation testing.
- Surveillance and/or audits of subcontractors, vendors, and/or suppliers.
- Review of objective evidence of the procurement document requirements based on such items as certifications, inspection reports, and logs.

Source/receipt inspection must be conducted for work in accordance with requirements contained in the *Inspection, Test, and Acceptance* institutional document. Before releasing items or material for use, workers must be provided access to quality verification documentation (e.g., receipt inspection reports and supplier documentation). Items or materials that are identified at any point in the acceptance process as not conforming to requirements must be documented using a nonconformance control process (e.g., nonconformance reports [NCRs]) and dispositioned and segregated (as practical to preclude use) until an approved disposition is implemented.

7.2.7 Commercial Grade Items, Government Furnished Equipment, and LANL Customized Items

Procedures must be established for setting requirements for inspecting, testing, and reviewing quality verification documents to establish the pedigree of items used in higher risk applications. Specifically, requirements for items not provided for use under an approved quality assurance program or items needed for higher risk applications than was specified at purchase or when developed. This dedication of items for a higher risk use must be addressed for:

- Commercial Grade Items (click here for the *Commercial Grade Item Dedication* institutional document).
- Government Furnished Equipment.
- LANL customized items.

Criterion 8 – Inspection and Acceptance Testing

8.1 Summary

The intent of inspection and acceptance testing is to assure that specified items, services, and processes are inspected and tested using acceptance and performance criteria using calibrated M&TE.

8.2 Process Requirements

8.2.1 Planning Inspection and Acceptance Testing

Qualified workers must be responsible for inspection and witnessing/verifying acceptance testing activities by implementing the requirements contained in the *Inspection, Test, and Acceptance* institutional document. Responsible managers must ensure that detailed test plans and procedures are identified and developed based on the requirements derived from implementing the design process and referenced industrial codes and standards, including LANL engineering standards contained in LIR 220-03-01, *Engineering Standards*.

Approved procedures, drawings, and specifications must determine:

- Extent of the inspection and/or testing.
- Characteristics and the attributes to be inspected and/or tested.
- M&TE required and its calibration requirements.
- Prerequisites and precautions that enhance or ensure safety.
- Parameters and acceptance criteria to be used.
- Documentation required to establish credibility.

Inspection and acceptance testing activities must be planned, scheduled, and conducted by technically qualified workers who have the authority to access appropriate information and facilities in order to verify acceptance and in accordance with approved test procedures/plans that include accept/reject criteria. These test plans/procedures must require verification of the correct installation and operability of all components, software, and system interlocks important to safety or to the quality of the deliverable. Test plans must address current equipment listings (e.g., master equipment list [MEL]) including process equipment. This list must identify all the structures, systems, and components that are important to the administration of the test or inspection. The results of these tests must be part of the records requirements for the process.

8.2.2 Inspection and Acceptance Testing Workers, Facilities, and Equipment

The responsible manager must provide appropriate facilities and equipment to trained and qualified workers to enable performance of the inspections or tests. Qualification records of inspection/test workers must be maintained.

8.2.3 Using Measuring and Test Equipment

When M&TE is required in an inspection or test activity, the selection and procurement process ensures that these items are of the proper type, range, accuracy, and tolerance to provide all information necessary to ensure the viability of the test or inspection. M&TE for inspection and testing activities conducted by qualified workers, and for subcontractor

activities, must be selected and procured in accordance with the requirements contained in the *Laboratory Calibration Program* institutional document. This document defines the program for calibration and control of M&TE that is traceable to the National Institute of Standards and Technology (NIST).

At a minimum, all components that require calibration to ensure the safety and viability of the process activity/results must be identified and calibrated by instruments traceable to NIST standards.

A graded approach for the calibration of equipment must be used, depending on the critical nature of the equipment as it applies to the desired end product. When specified, calibration must be conducted in accordance with the manufacturers' recommendations regarding maintenance and service schedules.

M&TE used by workers for inspection and testing activities must be calibrated and controlled in accordance with the above paragraph. M&TE used by subcontractors must be calibrated and controlled in accordance with the Laboratory Calibration Program or the subcontractor's LANL-approved quality assurance program and/or procedures. LANL workers must monitor the subcontractor's use and control of M&TE through surveillances and assessments conducted in accordance with approved procedures.

8.2.4 Performing Inspections and Acceptance Testing

8.2.4.1 Work Inspections

Work inspection activities must be performed by workers trained and qualified in accordance with procedures specifying required qualifications. Inspection activities that are required to verify conformance of an item or activity to specified requirements must be planned, with characteristics identified, methods of inspection and acceptance criteria established, and inspection results reported and documented in accordance with approved procedures.

Work inspection activities must include the inspection, identification, evaluation, and disposition of S/CI installed in safety applications (those whose failures could adversely affect the environment or the safety or health of the public or workers) or safety systems (in nuclear/radiological facilities) that may create potential hazards. In addition to the conditions specified in the above paragraph, inspection activities must be implemented in accordance with the requirements contained in the *Suspect/Counterfeit Items* institutional document.

Engineering evaluations and disposition of S/CI installed in safety applications/ systems must consider potential risks to the public and workers and the cost benefit impact, including a schedule for replacement (if required). The LANL NCR process links to the Unreviewed Safety Question (USQ) process. S/CI identified in non-safety applications during routine inspection or maintenance must be reported, evaluated, and dispositioned to prevent future use in safety applications.

8.2.4.2 Hold Points

Inspection hold points may be determined by the engineer, the person-in-charge (PIC), or qualified workers and stipulated in contract or work/change control documents. When inspection hold points are reached beyond which work cannot proceed without the specific consent of the inspector, workers/subcontractors must notify the responsible inspector, who must accept the work before work can resume. The inspector, in accordance with identified procedures, must document the results of the inspection. Waivers of hold points may be authorized only by the organization establishing the hold point.

8.2.4.3 In-Process Inspections

Qualified inspectors must perform in-process inspections as specified in approved procedures, and the results of these inspections must be documented. Monitoring of work processes must be accomplished by qualified workers and the results documented.

8.2.4.4 Acceptance Testing

Acceptance testing activities must be performed by qualified workers under controlled conditions. The organization responsible for the design of the item must provide the testing requirements and acceptance criteria developed to ensure proper installation and operability. This information must be included in specific acceptance testing plans and design package documentation used to conduct the test in accordance with identified procedures for materials testing and acceptance testing.

All S/CI must be dispositioned and tested (as necessary) using approved engineering test methods. Upon discovery of an S/CI, a nonconformance report must be issued in accordance with the requirements of the *Nonconformance Reporting* institutional document.

8.2.5 Inspection and Test Results Documentation/Records

Inspection and acceptance testing results must be documented in accordance with the procedure or plan used to conduct the inspection or test, consistent with the requirements contained in the *Inspection, Test, and Acceptance* institutional document.

ASSESSMENT CRITERIA

Criterion 9 – Management Assessment

9.1 Summary

The intent of a management assessment is for responsible managers to evaluate their organization's safety, security, and quality programs and processes and correct identified problems. This includes assessment of the effectiveness of management controls, adequacy of resources and workers assigned to perform work, technical and programmatic verifications to support LANL missions, and compliance with requirements.

9.2 Process Requirements

9.2.1 Performance Objectives

Management assessments are the primary method of improving performance and process quality by responsible managers. Management assessments include, but are not limited to, self-assessments/evaluations, walk-arounds, critiques, reviews, and appraisals. Assessments must be planned and performed to verify compliance with selected aspects of the quality program and to determine its effectiveness. Responsible managers must perform these assessments in accordance with written procedures or checklists (LIR 307-01-01, *Management Assessment Program*, and LIR 307-01-03, *Management Safety Walk-Arounds*).

Direct participation by responsible managers is essential to the success of the assessment process because they are in a position to evaluate the organization as a total system and to effect change. Management assessment results must be: documented through a corrective action process as outlined in Criterion 3 – Quality Improvement (e.g., Issues Management Program), reported to, and reviewed by senior management. Feedback and continuous improvement processes must include trend analysis and Lessons Learned Reports.

9.2.2 Management Assessments

Responsible managers must conduct objective and thorough management assessments representative of all work they are responsible for, including the activities required by this QAP. Management assessments must be conducted at intervals in accordance with approved procedures and must include those projects or programs lasting less than one year. Results from management assessments must be formally documented and reported to the next level of management.

9.2.3 LANL Self-Assessment Processes

LANL managers provide the primary means for the oversight and reporting of safety, security, environment, and high-risk activities for all work and activities conducted by Laboratory workers. These managers must be responsible for verifying and assessing:

- Events classified as reportable occurrences and other operating anomalies.
- Authorization basis issues, including USQs and hazards analyses.
- Data provided by external assessments.
- Appendix F self-assessments.
- Proposed and existing activities to ensure they meet health and safety requirements.

Criterion 10 – Independent Assessment

10.1 Summary

The intent of an independent assessment is to evaluate acceptability of work performance and products. Independent assessments are performed by technically qualified and knowledgeable personnel with sufficient authority and freedom from the organization being assessed.

10.2 Process Requirements

Independent assessments of QAPs and quality assurance areas will be performed by the Assessments Group (AA-2) based on an annual analysis of institutional risk. Internal assessments are also performed by individual organizations with auditors qualified to quality assurance standards. Independent assessments must be performed in accordance with the requirements contained in the *Independent Assessment* institutional document. The schedules for assessing the quality assurance areas are based on recurring problems, potential benefits, and management direction and are the responsibility of the individual organizations.

Quality Assurance Requirements and Standards Crosswalk

LANL QAP		DOE O 414.1B		NQA-1-2000, Part I		QC-1, Rev 10		ANSI/ASQ Z1.13-1999	
1.	**Program Development**	**1.**	**Program**	**1.**	**Organization**	**1.0**	**Introduction**	**1.0**	**Scope and Field of Application**
1.1 **1.2** **Requirements** **1.3** **LANL Roles and Respon-sibilities** **1.4** **LANL Quality Assurance Planning, Development, and Implementatio n**	**Summary** **Process**	(a) (b)	Establish organizational structure, functional responsibilities, levels of authorities and interfaces for those performing and assessing work. Establish management processes, including planning, scheduling and providing resources for work.	100 200 300 **2.** Basic 100 (a)	Basic Structure and Responsibility Interface Control **Quality Assurance Program**	**2.0** **2.2** **2.3** **2.5** **2.6** **3.0** **4.0**	**Basic Requirements** **Quality Management Program** 2.2.1 Submittal, Approval, Implementation and Reporting **Organization** **Establishing and Validating Requirements** **Planning** **Quality Requirements** **Responsibilities**	**5.0** **5.1** **5.2** **5.3**	**Institutional Quality Management Program** **Planning** **Leadership** **Support for the Performance of Research** Roles, Responsibilities and Authorities
2.	**Personnel Training and Qualification**		**Personnel Training and Qualification**	**2.**	**Quality Assurance Program**	**3.2**	**Training**	**5.3.1**	**Human Resources** - Management and Technical Training - Education, Experience and Skills
2.1 **2.2**	**Summary** **Process Requirements**	(a)	Train and qualify personnel to be capable of performing assigned work.	100	Basic			**5.5.3**	**Training**

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		(b)	Provide continuing training to personnel to maintain job proficiency	(b) 200 300 400 500	Indoctrination and Training Qualification Requirements Certification of Qualification Records				
3.	**Quality Improvement**	**3.**	**Quality Improvement**	**15.**	**Control of Non-Conforming Items**	**2.7**	**Metrics**	**5.5**	**Quality Improvement**
3.1 **3.2**	**Summary** **Process Requirements**	(a) (b) (c) (d)	Establish and implement processes to detect and prevent quality problems. Identify, control, and correct items, services, and processes that do not meet established requirements. Identify the causes of problems and include prevention of recurrence as a part of corrective action planning. Review item characteristics, process implementation, and other quality-related information identify items, services and processes needing improvement.	100 200 300 400 **16.** 100	Basic Identification Segregation Disposition **Corrective Actions** Basic	**3.1** **3.12** **3.13**	**Quality Improvement** 3.1.1 Continuous Improvement 3.1.2 Prevention vs. Detection 3.1.3 Quality Cost Management **Nonconformance** 3.12.1 NC Item Control 3.12.2 NC Item Disposition **Corrective Action**		5.5.1 Principles 5.5.2 Quality Improvement Goals

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4.	**Document Control and Records Management**	**4.**	**Documents and Records**	**6.**	**Document Control**	**3.14**	**Records**	**4.3**	**Performing and Documenting**
4.1 **4.2**	**Summary** **Process Requirements**	(a) (b)	Prepare, review, approve, issue, use and revise documents to prescribe processes, specify requirements, or establish design. Specify, prepare, review, approve, and maintain records	100 200 300 **1.7** 100 200 300 400 500 600 700 800	Basic Document Control Document Changes **Quality Assurance Records** Basic Generation of Records Authentication of Records Classification Receipt Control and Retention of Records Storage Disposition Maintenance of Records	**3.4** **3.5**	**Instructions, Procedures, and Drawings** **Document Control**	**5.3.2**	**Research Material Resources** - Institutional system for safe storage and retrieval of research Records.
5.	**Work Processes**	**5.**	**Work Processes**	**5.**	**Instruction, Procedures and Drawings**	**3.4**	**Instructions, Procedures, and Drawings**	**4.1**	**Responsibility for the Research**
5.1 **5.2**	**Summary** **Process Requirements**	(a)	Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using	100 **8.** 100 200 300	Basic **Identification and Control of Items** Basic Identification Methods Specific Requirements	**3.7**	**Identification, Control, and Status of Items** 3.7.1 Tooling and Fixtures 3.7.2 Limited Life Materials and	**4.2**	**Planning the Research** 4.2.1 Technical Approach 4.2.2 Scheduling and Deliverables

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			approved instructions, procedures, etc. (b) Identify and control items to ensure their proper use. (c) Maintain items to prevent their damage, loss or deterioration. (d) Calibrate and maintain equipment used for process monitoring or data collection.	**9.** 100 200 300 400 **12.** 100 200 300 400 **13.** 100 200 300 400 500 600 **14.** 100	**Control of Special Processes** Basic Process Control Responsibility Records **Control of Measuring and Test Equipment** Basic Selection Calibration & Control Records **Handling, Storage, and Shipping** Basic Special Requirements Procedures Tools and Equipment Operators Marking or Labeling **Inspection, Test, and Operating Status** Basic	Components 3.7.3 Materials and Items Designated for Destructive Testing 3.7.4 Special Instructions and Environments **3.8** **Control of Processes** 3.8.1 Process Control Methods 3.8.2 Special Processes **3.10** **Control of Measuring and Test Equipment** **3.11** **Handling, Storage, Packaging and Delivery** 3.11.1 Government Furnished Material 3.11.2 NNSA-Accepted Material	4.2.3 Facilities and Requirements **4.3** **Performance and Documentation of the Research** **Transferring the Results of the** **4.5** **Research**	
6.	**Design**	**6.**	**Design**	**3.**	**Design Control**	**2.4**	**Early and Continuous**	**5.3.2**	**Material Resources** - Design & Constuc-

LANL QAP		DOE O 414.1B		NQA-1-2000, Part I		QC-1, Rev 10		ANSI/ASQ Z1.13-1999	
							Application of Quality Principles		tion of research, facilities, fabricated research facilities and apparatus. - Design of support-computer software
6.1 **6.2**	**Summary** **Process Requirements**	(a) (b) (c) (d) (e)	Design items and processes using sound engineering/scientific principles and appropriate standards. Incorporate applicable requirements and design bases in design work and design changes. Identify and control design interfaces. Verify/validate the adequacy of design products using individuals or groups other than those who performed the work. Verify/validate work before approval and implementation of the design.	100 200 300 400 500 600 700 800 900	Basic Design Input Design Process Design Analyses Design Verification Change Control Interface Control Software Design Control Documentation and Records	**3.3** **3.3.1** **3.3.2** **3.3.3** **3.3.4** **3.3.5** **3.3.6** **3.3.7** **3.16**	**Design** **Design Input** **Design Process** **Design Verification (Reviews & Qualification)** **Design Documents** **Design Change Control and Configuration Management** **Interface Control** **Records** **Software Quality Assurance**		
7.	**Procurement**	**7.**	**Procurement**	**4.**	**Procurement Document Control**	**3.6**	**Procurement**	**5.3.2**	**Material Resources** - Procured items and services
7.1 **7.2**	**Summary** **Process Requirements**	(a)	Procure items and services that meet established requirements and perform as specified.	100 200 300	Basic Content of the Procurement Documents Procurement	**3.6.1** **3.6.2**	**Supplier Evaluation, Selection and Monitoring** **Procurement**		

LANL QAP		DOE O 414.1B		NQA-1-2000, Part I		QC-1, Rev 10		ANSI/ASQ Z1.13-1999	
		(b) (c)	Evaluate and select prospective suppliers on the basis of specified criteria. Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and service.	 400 **7.** 100 200 300 400 500 600 700	Document Review Procurement Document Changes **Control of Purchased Items and Services** Basic Supplier Evaluation and Selection Bid Evaluation Control of Supplier-Generated Documents Acceptance of Item or Service Control of Supplier Nonconformances Commericial Grade Items	**3.6.3** **3.6.4**	**Documentation Acceptance of Procured Items, Materials and Services** **Certificate of Conformance**		
8.	**Inspection and Acceptance Testing**	**8.**	**Inspection and Acceptance Testing**	**10.**	**Inspection**	**3.9**	**Inspection, Test, and Acceptance**	**5.3.2**	**Material Resources** - Institutional services to identify and minimize uncertainties associated with measurements. - Analytical or Inspection services

LANL QAP		DOE O 414.1B		NQA-1-2000, Part I		QC-1, Rev 10		ANSI/ASQ Z1.13-1999	
8.1 **8.2**	**Summary** **Process Requirements**	(a) (b)	Inspect and test specified items, services, and processes using established acceptance and performance criteria. Calibrate and maintain equipment used for inspection and tests.	100 200 300 400 500 600 700 **11.** 100 200 300 400 500 600 **12.** 100 200 300 400	Basic Inspection Requirements Inspection Hold Points Inspection Planning In-process Inspections Final Inspection Records **Test Control** Basic Test Requirements Test Procedures Computer Program Test Procedures Test Results Test Records **Control of Measuring and Test Equipment** Basic Selection Calibration & Control Records	**3.10**	**Control of Measuring and Test Equipment**		
9.	**Management Assessment**	**9.**	**Management Assessment**	**2.**	**Quality Assurance Program**	**3.15**	**Assessments** 3.15.2 Scheduling 3.15.3 Planning 3.15.4 Performance 3.15.5 Reporting	**4.4**	**Assessing the performance of the research**
9.1 **9.2**	**Summary** **Process**	(a)	Ensure that managers assess their manage-	100 (c)	Basic			**5.4**	**Assessment** 5.4.2 Support

LANL QAP		DOE O 414.1B		NQA-1-2000, Part I		QC-1, Rev 10		ANSI/ASQ Z1.13-1999	
	Requirements		ment processes and identify and correct problems that hinder the organization from achieving its objectives.						Activities 5.4.4 Personnel Performance 5.4.5 Data Utilization
10.	**Independent Assessment**	**10.**	**Independent Assessment**	**18.**	**Audits**	**3.15**	**Assessments** 3.15.1 Assessor Qualification 3.15.2 Scheduling 3.15.3 Planning 3.15.4 Performance 3.15.5 Reporting	**5.4**	**Assessments** 5.4.1 Research Review 5.4.3 Management Activities
10.1 **10.2**	**Summary Process Requirements**	(a) (b) (c)	Plan and conduct independent assess-ments to measure items and service quality and the adequacy of work performance, and to promote improvement. Establish sufficient authority and freedom from line management for independent assessment teams. Ensure that persons conducting independ-ent assessments are technically qualified and knowledgeable in the areas to be assessed.	100 200 300 400 500 600 700 800	Basic Scheduling Preparation Performance Reporting Response Follow-up Action Records				

Software Quality Assurance Program

1. Purpose and Scope

This summary of the Institutional Software Quality Management (ISQM) Program presents an overview of the institutional software quality assurance and software management policies and processes. Implementation of these software policies and processes enables institutional compliance with Department of Energy (DOE), National Nuclear Security Administration (NNSA), and contractual and regulatory requirements applicable to the Los Alamos National Laboratory.

Per DOE O 414.1 (current contractual version), *Quality Assurance*, LANL is responsible for complying with the safety software requirements of the Contractor Requirements Document (CRD). In addition, when activities affect the safety of DOE (including NNSA) nuclear facilities, LANL must conduct work in accordance with the quality assurance requirements in the Code of Federal Regulations, Title 10, Part 830, Subpart A, *Nuclear Safety Management Quality Assurance*, and Subpart B, *Safety Basis Requirements*. Additional software activities are covered by requirements such as DOE/NNSA *Weapon Quality Policy* (QC-1), Revision 10. LANL is responsible for compliance with the requirements of division (and subcontractor) implementation plans. DOE O 414.1 (current contractual version) states that these plans must be developed and implemented using voluntary national or international consensus standards.

2. Applicability

LANL's Software Quality Assurance Program (SQAP) is the ISQM Program. The requirements included within the SQAP apply to all software products acquired, developed, or modified at LANL. This includes administrative, operations, and programmatic software along with software-related activities conducted by members of the LANL workforce. Subcontractors and suppliers are covered through the flow-down of requirements in LANL procurement contract terms and conditions.

Through the implementation of LIR 308-00-05, *Software Quality Management*, the SQAP addresses the following regulatory and contractual drivers:

- 10CFR830, Subpart A, *Nuclear Safety Management Quality Assurance*.
- 10CFR830, Subpart B, *Safety Basis Requirements*.
- DOE O 414.1 (current contractual version), *Quality Assurance*.
- DOE/NNSA QC-1, Revision 10, Section 3, Criterion 16, *Weapons Quality Policy: Software Quality Assurance*.
- DOE O 200.1, *Information Management*.
- DOE O 413.3, *Program and Project Management for the Acquisition of Capital Assets*.
- DOE O 420.1A, *Facility Safety*.

An area of significant focus is safety software. Safety software is software that performs a safety system function as part of a structure, system, or component (SSC) that has been functionally classified as safety class (SC) or safety significant (SS) or is software whose failure could result in missed surveillances, confusion regarding system status, noncompliance with nuclear safety regulatory laws, environmental permits, or regulations and/or commitments to compliance. These requirements complement those of

10CFR830, Subpart A, and provide detail for work associated with safety software that is conducted under the nuclear facility QAP.

The SQAP is designed to ensure continuous software process improvement by providing an industry standard process-based software engineering model. LANL's processes will be based on the Carnegie-Mellon University (CMU) Software Engineering Institute's (SEI) Capability Maturity Model Integrated (CMMI, version 1.1) that is supported by the Department of Defense (DOD) as well on IEEE Standards on Software. LANL will use these models to demonstrate that it has a measurable approach for managing software. LANL will define appropriate levels of rigor and explicit quality goals that will increase the confidence in and credibility of LANL software. At the software project level, management processes are covered by division SQM plans to implement key processes for category 1 and 2 projects as required in LIR 308-00-05, *Software Quality Management*.

The SQAP assigns roles, responsibilities, authorities, and accountabilities, defines policies and requirements, provides for the performance and assessment of work, and enables identification and application of improvement initiatives. The SQAP description and the SQM LIR/LIG are living documents under the change control direction of LANL's Office of the CIO, with advice from the Software Engineering Process Group (SEPG).

The SEPG, in accordance with the requirements stated in the SEPG Charter, serves as a focal point for defining, maintaining, and improving LANL's software processes. The SEPG develops Laboratory guidance, information, and standards to provide a higher degree of confidence and credibility in the software produced by the lab and programs that will implement SQM. Membership is open to all software developers and managers. Members participate in process development and enhancement. Membership will also include designated representatives for each division or major contractor. The designated members will have voting rights on policy guidelines issued by the SEPG in a steering subcommittee. The SEPG responsibilities include but are not limited to:

- Developing support material for the nine process areas identified in LIR 308-00-05.
- Developing support material for any institutional key practice areas that were out of scope for the LIR.
- Developing support material for the SQAP.
- Responding to Requests for Comment (RFCs) as subject matter experts on software engineering, quality, and development.
- Hosting the CIO Colloquium on Software.
- Providing information exchange in the area of computer science and software development, quality, and engineering.
- Executing laboratory software quality requirements and ensuring flow-down to local SEPGs and the worker level within their divisions.

3. Software Quality Management LIR 308-00-05

LIR 308-00-05, *Software Quality Management*, addresses the aforementioned and other requirements as noted in DOE O 414.1 (current contractual version) including software with significant importance to mission, protection of assets, or avoiding adverse publicity if said software failed. The scope of laboratory-wide software quality management touches all LANL divisions, programs, and offices that

develop, acquire, or modify software.

LANL supports the implementation of tailored formal controls consistent with the possible effects of software failure. Appendices A and B of LIR 308-00-05 contain the Risk Based Graded Approach form for categorization and guidance used for this tailoring. The categorization is based on the probability that a critical software failure might occur and the impact that could result in the areas of safety, security, health, the environment, or LANL programs.

All software that has been or is currently being developed, modified, or acquired and performs calculations or data transformations that will be relied upon by more than one person, or affects the health/safety, security, environmental or programmatic impact areas ("in-scope" as defined in LIR 308-00-05) within each division must be identified, categorized, and inventoried. The categorization is performed using the Risk-Based Graded Approach form contained within the LIR. The Software Inventory Management System (SWIMS) will be used to maintain the institution's software inventory.

Divisions may refine the definition of software in LIR 308-00-05 to fit the role software has within their division and create a division statement of scope. The statement of scope must not contradict the intent of the LIR. Rather, it must clarify the definition of "in-scope" within the context of the division. The statement of scope will be approved by the Division Leader and become division policy after concurrence of the LANL CIO. As a good business practice, divisions will be encouraged to apply the principles of SQM to all software including that deemed "out of scope."

Implementation of LIR requirements is executed at the division level as identified in the laboratory organizational charts, including some project offices. In addition, some large-scale high-risk projects (systems or software projects) may be asked to consider developing their own implementation plans (e.g., Enterprise Project, CMR Replacement Project) but are not required to do so. They are asked to do so in a proactive manner to demonstrate their direction to reduce risk and to embrace best practices and performance excellence in software engineering.

4. Quality Assurance Criteria Implementation

The ISQM program complies with the 10 quality criteria as defined in 10CFR830, Subpart A, *Nuclear Safety Management Quality Assurance*, and must be applied to LANL work as good business practices for planning, managing, achieving, and assessing work in a safe, secure, and compliant manner. Detailed process descriptions are defined in the ISQM Program document. The 10 criteria are applied and implemented in accordance with Risk Management/Formality Levels using the graded approach.

In addition, LANL takes a management systems approach to integrate the applicable DOE Orders and other customer requirements, including adherence to CFRs. LANL organizations systematically plan, perform, evaluate, and improve work processes and products, applying the 10 criteria and implementing the *Software Quality Management* LIR (308-00-05) at the division level. Division software quality management plans may incorporate other customer requirements such as: DOE/NNSA QC-1 (Section 3, Criterion 16, *Weapons Quality Policy: Software Quality Assurance*), ASME NQA-1-2000, etc., as appropriate to prescribe more detailed requirements.

INTEGRATION OF ISMS AND QA INTO WORK MANAGEMENT

Integrated Safety Management System (ISMS) Five-Step Work Process	Integrated Work Management (ISMS and QA) (Refer to QAP Criteria Sections)	10 Quality Assurance Criteria
1. Define the Scope of Work • Translate mission into work • Set expectations • Prioritize tasks and allocate resources	Determine Responsibilities and Resources • Project plans • Work plans • Work scopes and contracts	Criterion 1 – Program • Plan, manage Criterion 2 – Personnel Training and Qualification • Train, qualify
2. Analyze the Hazards • Identify and analyze hazards • Categorize hazards	Plan Management of Risks and Hazards • Analyze work details for risks and hazards • Include public and worker • Include facility and activity	Criterion 1 – Program • Plan and manage priorities and risks (Graded Approach) Criterion 3 – Quality Improvement • Prevent hazards and risks
3. Develop and Implement the Controls • Identify standards and requirements • Identify controls to prevent/ mitigate hazards • Establish safety envelope • Implement controls	Prescribe Detailed Controls • Documented safety analyses • Facility safety plans • Activity hazard analyses • Integrated work documents • Procurement/contract criteria • Policies and procedures using a graded approach to address risks and hazards	Criterion 4 – Documents and Records • Develop controlled instructions, procedures, and drawings Criterion 6 – Design • Control of design output documents
4. Perform the Work • Confirm readiness • Perform work safely	Implement Work • Work authorization documents • Policies and procedures • Integrated work documents • Procurement contracts • Drawings, inspections, tests meeting Quality Criteria and safety bases	Criterion 5 – Work Processes • Implement procedures, instructions, and drawings Criterion 7 – Procurement • Develop procurement contracts Criterion 8 – Inspection and Acceptance Testing • Perform inspection and acceptance testing
5. Ensure Performance • Collect feedback information • Identify improvement opportunities • Make changes to improve • Oversight and enforcement • Reinforcement and accountability	Assess and Improve Work Management through • Assessments/Audits • Nonconformances • Lessons Learned Re-analyze safety work/risks • Update policies, procedures, and controlled documents • Improve implementation tools and processes	Criterion 3 – Quality Improvement • Correct deficiencies • Preclude recurrence Criterion 9 – Management Assessment • Conduct self-assessments and evaluations Criterion 10 – Independent Assessment • Evaluate the effectiveness of management systems